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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,121	08/16/2001	Yves Dellmotte	CRT-543(J417SP585)	8727
26959	7590	10/15/2004	EXAMINER	
MONIQUE A. MORNEAULT 311 S. WACKER DRIVE 53RD FLOOR CHICAGO, IL 60606-6622			VO. HAI	
			ART UNIT	PAPER NUMBER
			1771	

DATE MAILED: 10/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/831,121

Applicant(s)

DELLMOTTE ET AL.

Examiner

Hai Vo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-134 is/are pending in the application.
- 4a) Of the above claim(s) 90-130 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46-89 and 131-134 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 0304.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 46-89 and 131-134 in the reply filed on 03/22/2004 is acknowledged.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 46-55, 60-83, 89, and 131-134 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 366 564 (hereafter EP'564). EP'564 teaches an antithrombic medical material comprising a support formed from expanded polytetrafluoroethylene (PTFE) and a fibrin network covering the support. It appears that EP'564 uses the porous PTFE to form a support as Applicants, therefore, it is not seen that the support would have performed differently than that of the present invention in terms of hydrophobic properties and pore/node structure as recited in the claims. This is in line with *In re Spada*, 15 USPQ 2d 1655 (1990) which holds that products of identical chemical composition can not have mutually exclusive properties. Further, EP'564 teaches a process of making the fibrin membrane on the surface of the porous support wherein the fibrin membrane was washed with a saline solution to remove the excess reaction solution (example 1). Likewise, it is clearly apparent that very little or no reacting fibrinogens were left within the fibrin membrane after the saline solution treatment; i.e., the fibrin membrane substantially

free of unbound fibrinogen covering the face of the porous support. This reads on Applicants' fibrin network containing less than 0.1% by weight of fibrinogen that has not reacted. EP'564 teaches the fibrin permeated the pores in the e-PTFE graft tube. This reads on the fibrin network being positioned over a portion of the pores and the fibrin network substantially uniform and homogeneous. The fibrin layer has a thickness of 20 microns (page 11, line 47) within the claimed range. The EP'564 appears to use a thrombin solution containing Factor XIII and a fibrinogen solution to form the fibrin membrane. The medical device of EP'564 serves for the same purposes. Therefore, it is the examiner's position that a network of adjacent alveoli, cell structure, moisture content, fibronectin content, calcium content would be inherently present so as to enable the medical device to effectively function as an implant, an artificial skin. This is in line with *Ex parte Tummers et al.* 137 USPQ 444 which holds that if the chemical composition of the claimed article of manufacture recited in the claims is the same as the identical structure of the prior art, it is immaterial that the applicant recognized different advantages flowing therefrom than did the prior art. The fibrin layer is formed from a plasmin solution which substantially contains water soluble proteins and sugars. The recitation that the element is a "an filter" has not given patentable weight because it has been held that a preamble is denied the effect of a limitation where the claim is drawn to a structure and the portion of the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory

clause. **Kropa v. Robie**, 88 USPQ 478 (CCPA 1951). It is the examiner's position that EP'564 anticipates the claimed subject matter.

4. Claims 46, 48-50, 52, 53, 60-89, and 131-134 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/22115. US 5,989,215 to Delmotte et al is relied on as an equivalent form of WO 96/22115. Delmotte teaches a fibrin delivery device comprising a fibrin film that has two or more layers (column 6, lines 30-35). Figure 6A and 6B show that the fibrin film has at least two pores spaced from each other by a node. The fibrin film contains less than 1% by weight of fibrinogen in terms of the total dry weight of the fibrinogen and fibrin (column 6, lines 65-67). Likewise, the fibrin network is substantially free of unbound fibrinogen covering a portion of the support face. The thickness of the fibrin barrier material is at least 20 microns within the claimed range (column 6, lines 35-40). The fibrin network being positioned over a portion of the pores and the fibrin network substantially uniform and homogeneous (column 5, lines 40-44). The fibrin layer has a pore with an average pore size of below 20 microns. When the two fibrin layers are adjacent to each other, it is expected that the fibrin network at one layer would inherently extends through the pores of the other fibrin layers. It appears that Delmotte uses the same solutions to form the fibrin membrane and the medical material of Delmotte serves for the same purposes. Therefore, it is the examiner's position that a network of adjacent alveoli, cell structure, moisture content, fibronectin content, calcium content would be inherently present so as to enable the medical device to effectively function as an implant, an artificial skin. This is in line with **Ex parte Tummers et al**. 137 USPQ

444 which holds that if the chemical composition of the claimed article of manufacture recited in the claims is the same as the identical structure of the prior art, it is immaterial that the applicant recognized different advantages flowing therefrom than did the prior art. The fibrin layer contains water soluble proteins and sugars (column 7, lines 10-15, column 8, lines 5-15). The fibrin layer itself is a biocompatible support (column 5, lines 25-27). The recitation that the element is a "an filter" has not given patentable weight because it has been held that a preamble is denied the effect of a limitation where the claim is drawn to a structure and the portion of the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clause. ***Kropa v. Robie***, 88 USPQ 478 (CCPA 1951). It is the examiner's position that Delmotte anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
6. Claims 56-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 366 564. EP'564 teaches the fibrin network extends through the pores of the support. However, EP'564 does not specifically teach how far the fibrin network extends through the pores of the support. Since the depth of the support through which the fibrin network extends is recognized as a result-effective variable,

differences in the depth of the support will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such depth is critical or provides unexpected results. Therefore, in the absence of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the element wherein the fibrin network permeates through the pores to a depth of the support instantly claimed motivated by the desire to promote the adhesion between the support and fibrin network. This is in line with *In re Aller*, 105 USPQ 233 which holds discovering the optimum or workable ranges involves only routine skill in the art.

7. Claims 84-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 366 564 as applied to claim 46 above in view of WO 96/22115. EP'564 does not specifically disclose the fibrin membrane comprising a second fibrin network superimposed on a first fibrin network. Delmotte teaches a fibrin delivery device comprising a fibrin film that has two or more fibrin layers (column 6, lines 30-35). The fibrin layers, each comprise pores with different pore sizes (column 14, lines 10-25). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to motivated by the desire to use the fibrin membrane having two fibrin layers with different pore sizes motivated by the desire to provide the fibrin membrane having a double coating, one for a biomechanical barrier coating and another for achievement of hemostasis and wound repair.
8. Claims 56-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over by WO 96/22115. Delmotte teaches the fibrin layer having a pore with an average pore

size of below 20 microns. When the two fibrin layers are adjacent to each other, it is expected that the fibrin network at one layer would inherently extend through the pores of the other fibrin layers. Delmotte does not specifically teach how far the fibrin network extends through the pores of the support. Since the depth of the support through which the fibrin network extends is recognized as a result-effective variable, differences in the depth of the support will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such depth is critical or provides unexpected results. Therefore, in the absence of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the element wherein the fibrin network permeates through the pores to a depth of the support instantly claimed motivated by the desire to promote the adhesion between the support and fibrin network. This is in line with *In re Aller*, 105 USPQ 233 which holds discovering the optimum or workable ranges involves only routine skill in the art.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hai Vo whose telephone number is (571) 272-1485. The examiner can normally be reached on M,T,Th, F, 7:00-4:30 and on alternating Wednesdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on (571) 272-1478. The fax

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phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

HV

Hai Vo

Tech Center 1700